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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,858	04/14/2000	James McShane	109536.132	9181

7590 11/20/2002  
Hollie L. Baker  
Hale and Dorr LLP  
60 State Street  
Boston, MA 02109

EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/549,858

Applicant(s)

MC SHANE ET AL.

Examiner

Dwayne C Jones

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on 24 SEP 01

2a) ☒ This action is **FINAL**.

2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-23 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 14 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-23 are pending.
2. Claims 1-23 are rejected.

### *Response to Arguments*

3. Applicant's arguments filed September 24, 2002 have been fully considered but they are not persuasive. Applicants make the following arguments. First, applicants argue that Oishi et al. is concerned only with oral dosage forms of benzimidazole compounds whereas the instant invention is directed to intravenous administration of the same compounds. Second, applicants also dispute that Takechi et al. teach of a pharmaceutical composition of a benzimidazole compound and nicotinamide.
4. In response to applicant's argument that Oishi et al. is concerned only with oral dosage forms of benzimidazole while the instant invention is directed to intravenous administration of the same compounds, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Accordingly, the instant claims are again rejected over the prior art reference of Oishi et al.

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5. With respect to Applicants' arguments that the claimed composition does not require additional ingredients such as nicotinamide, it is note that applicants' claims recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". See *Gould v. Mossinghoff, Comr. Pats.*, (DCDC 1982) 215 USPQ 310. Accordingly, Takechi et al. do render the instant claims obvious because Takechi et al. do in fact teach of a pharmaceutical composition of a benzimidazole compound and glycine.

6. Once again, the prior art reference of Takechi et al. teach of a stable injectable preparation, which has anti-ulcer activity and that contains an amino acid, namely glycine, and a benzimidazole compound. In addition, it is noted that Takechi et al. disclose of the addition of pH control agents, namely amino acids, to this pharmaceutical composition containing benzimidazole, (see column 10, lines 4-11).

### ***Drawings***

7. The Office Draftsperson has approved the drawings of April 14 2000.

### ***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Oishi et al. of H5-194225 is maintained and repeated. Oishi et al. teach of stabilized

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anti-ulcer preparations, which contain an amino acid, namely glycine, and a benzimidazole compound, (see claims 1,2 and 4). The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the benzimidazole genus as taught by Oishi et al., including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

10. The rejection of claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takechi et al. of U.S. Patent No. 5,536,735 is again maintained and repeated. Takechi et al. teach of a stable injectable preparation, which has anti-ulcer activity and that contains an amino acid, namely glycine, and a benzimidazole compound, (see columns 1,2,5,6 and column 8). In addition, it is noted that Takechi et al. disclose of the addition of pH control agents, namely amino acids, to this pharmaceutical composition containing benzimidazole, (see column 10, lines 4-11).

The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the benzimidazole genus as taught by Oishi et al., including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

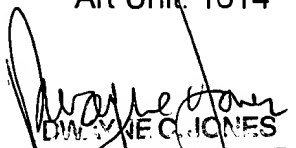
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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DW. M. E. C. JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
June 24, 2002